

**REMARKS**

Applicants respectfully request consideration of the application in view of the foregoing amendments and the following remarks.

Claim 1 is amended herein to more clearly point out the subject matter of the claimed invention. The amendment to claim 1 is supported, *inter alia*, by the original claims and by the specification on page 15, line 33- page 16, line 2 and page 16, lines 25-34. Claim 1 is further amended to replace "replication-defective chimpanzee vector" with "recombinant chimpanzee adenoviral vector" for purposes of clarity. Since the claimed vector is replication deficient due to a lack of E1 activity, the term "replication-deficient" is superfluous. Further, the addition of the term "recombinant" clarifies that the vector is made by recombinant DNA techniques.

Claims 6, 8, and 45 are amended herein for consistency with the amendment to the preamble of claim 1. Claims 44 and 46 are amended herein to be dependent on claim 1, as necessitated by the cancellation of claim 43. Claim 46 is further amended to replace "heterologous nucleic acid" with "transgene." The amendments are supported, *inter alia*, by the original claims.

Claim 50 is amended to replace the term "PER.C6™" with "a cell as deposited with the ECACC under accession number 96022940." A corresponding amendment was made to the paragraph appearing on page 28, lines 1-11 of the specification. This amendment is supported by WO97/00326 on page 30, lines 3-4, which was incorporated by reference in the application as filed. Applicants assert that the material inserted into the specification is the same material that was previously incorporated by reference; thus, the amendment adds no new matter. Claim 50 was further amended to indicate that the claimed cell propagates the recombinant adenoviral vector. This amendment is supported by the specification on page 28, lines 1-5.

New claims 51 and 52 were added. Claim 51 is supported, *inter alia*, by original claim 9 and by the specification on page 30, lines 24-28. Claim 52 is supported, *inter alia*, by original claims 7 and 18 and by the specification on page 21, lines 17-21 and page 22, lines 1-4 and 17-21.

No new matter has been added by the amendments to the claims or the new claims added herein.

Claim 43 is canceled without prejudice to pursuing the subject matter of said claim in a later filed divisional application.

### ***Claim Objections***

The Office Action states that claim 1 objected to because it states that the claimed vector comprises a sequence of nucleotides as set forth in SEQ ID NO:1; however, SEQ ID NO:1 is the whole genome of ChAd3, which does not have a deletion at E1. In response, Applicants have amended claim 1 to more clearly point out the subject matter of the invention. Specifically, the claim was amended to indicate that the claimed vector is "derived from SEQ ID NO:1." Applicants assert that the claim, as amended, unambiguously defines the subject matter of the claimed invention. Accordingly, it is respectfully requested that the objection to the claim be removed and the claim allowed.

The Office Action further states that claim 49 is objected-to for containing two ".,". Applicants thank the Examiner for pointing out this error and have corrected this oversight via this amendment. Accordingly, Applicants respectfully request that the objection to claim 49 has been overcome.

### ***Rejection under 35 USC 112, second paragraph***

Claims 6, 8, 43-46 and 48-50 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Specifically, the Office Action states that claim 43 is indefinite because the description of the claimed Ad vector simply by referencing the source of the adenovirus is not a sufficiently clear description of the claimed subject matter. Applicants respectfully note that the cancellation of claim 43 herein renders the instant rejection moot. Claims 44, 46, 48, and 49, which were dependent on claim 43, are amended herein to depend from claim 1, which specifies the nucleotide sequence by SEQ ID NO. Applicants additionally note that claim 45 is dependent on claim 1, not on claim 43, and thus the instant rejection is not applicable to claim 45.

Claim 50 is alleged to be indefinite for recitation of the trademark "PER.C6™". Claim 50 is further alleged to be indefinite because "293 cells and PER.C6 cells may be the starting cells for making a cell comprising the recombinant adenoviral vector of claim 43, but they are not the host cell comprising the adenoviral vector of claim 43." *See* Office Action at page 4, lines 4-6.

In response, Applicants have amended claim 50 to replace the term "PER.C6™" with "a cell as deposited with the ECACC under accession number 96022940," which provides

an unambiguous identification of the claimed cells. Applicants further amended the claim to indicate that the claimed cells propagate the recombinant adenoviral vector.

Applicants assert that the rejection of claims 44, 46 and 48-50 has been overcome by the amendments herein and that all of the cited claims are in compliance with 35 USC 112, paragraph 2. It is thus requested that the rejection be removed and the claims allowed.

Applicants respectfully traverse the rejection of claims 6 and 8 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Office Action fails to allege any specific reason why these claims are indefinite. Accordingly, it is requested that the rejection to these claims be removed and the claims allowed.

***Rejection under 35 USC 112, first paragraph***

Claims 1, 6, 8, 43-46 and 48-50 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the relevant art to make and/or use the claimed invention. Specifically, it is alleged that the invention employs novel biological materials that are essential to the invention of the cited claims, namely novel chimpanzee adenovirus 3 (ChAd3). It is further alleged that ChAd3 must therefore be obtainable by a repeatable method set forth in the specification or otherwise be available to the public. Applicants respectfully traverse.

According to MPEP § 2404.02, a biological deposit is not necessary, "even though specific biological materials are required to practice the invention if those biological materials can be made or isolated without undue experimentation." In the present case, Applicants assert that a biological deposit is not necessary because the claimed invention can be practiced based on the disclosure of the application as filed without undue experimentation. At the time the application was filed, one of ordinary skill in the art could make replication-defective ChAd3 vectors based on well-known, conventional techniques, in combination with the description set forth in the application. Notably, the application discloses the complete genomic sequence of chimpanzee adenovirus type 3 (see Figures 5A-5K and SEQ ID NO:1), which, at the time the application was filed, could be utilized to construct replication-defective vectors, host cells, and adenoviral particles in accordance with the claimed subject matter by following conventional techniques well-known in the art.

Moreover, the specification thoroughly describes methods for the production of replication-defective vectors according to the invention, which, coupled with the sequence information provided in the application as a starting point, could be followed by one of skill in the art to practice all of the claimed subject matter. See, e.g., page 17, line 1 to page 19, line 17 of the specification, which describes the construction of such vectors. See also, page 26, line 19

to page 29, line 19 of the specification. A detailed example is also provided in the application of specific methods that can be used to practice the claimed invention. See, e.g. Example 2, which describes the construction of replication-defective ChAd shuttle and expression vectors and rescue and amplification of the vectors from culture. Thus, Applicants submit that disclosure of the complete genomic sequence of ChAd3 in the application, together with the description provided in the specification and knowledge of conventional techniques that were well-known at the time the application was filed, would clearly allow one of skill in the art to practice the entire scope of the claimed invention. Accordingly, a biological deposit is not necessary to provide enablement of the cited claims in the instant case.

Applicants therefore respectfully request that the rejection of the claims as lacking enablement under 35 U.S.C. § 112, first paragraph be removed and the claims allowed.

***Summary***

Applicants assert that all claims are in condition for allowance and a favorable action on the merits is earnestly solicited.

If the Examiner believes that a telephone conference would be of value, he is requested to call the undersigned attorney at the number listed below.

Respectfully submitted,

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Date: February 16, 2012